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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,925	08/16/2005	Yoshinori Sato	NAGACO1.001APC	6147

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KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER
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GWARTNEY, ELIZABETH A

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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01/26/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,925	<b>Applicant(s)</b> SATO ET AL.	
	<b>Examiner</b> Elizabeth Gwartney	<b>Art Unit</b> 1794	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-11, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-11, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. The Amendment filed September 24, 2009 has been entered. Claims 4-6, 12 and 13 have been cancelled. Claims 1-3, 8-11, 14 and 15 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 7-11, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 1 and 10, while there is support in the specification for lactic acid polymer, which contains no lactic acid polymers other than poly-L-lactic acid polymer having a glass transition temperature of 55° to 80°C, there is no support for broadly reciting poly-L-lactic acid polymer.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 7-8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gin et al. (US 2004/0247669) in view of Bunczek et al. (US 6,013,287).

Regarding claim 1, 3 and 7, Gin et al. disclose a gum base composition comprising gum base and about 6.36% to about 6.5% by weight hydrophilic polymer including pure L-lactic acid polymer with a number average molecular weight in the range of approximately 10,000 to 125,000 ([0010], [0032], [0041], [0184]-[0195]).

While it is recognized that Gin et al. disclose the number average molecular weight ( $M_n$ ) of the poly-L-lactic acid while the present claims require weight average molecular weight ( $M_w$ ),

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given the relationship between  $M_w$  and  $M_n$ , i.e.  $M_w/M_n > 1$ , it is clear that the weight average molecular weight of Gin et al. would overlap that presently claimed.

Further, note, given Gin et al. disclose the interchangeability of hydrophilic polymers including ETHOCEL and pure L-lactic acid polymer, the amount of hydrophilic polymer was determined using gum formulations 13 and 14 on p. 13 (wherein the amount of hydrophilic polymer in the gum base composition equals the weight of hydrophilic polymer divided by the total weight of the gum base composition; i.e. 0.4 g/6.18 g (formulation 13) and 0.4 g/6.28 g (formulation 14)).

Given Gin et al. disclose a polymer identical to that presently claimed, intrinsically it would have a crystallinity of 20% or less.

While Gin et al. disclose that the gum base comprises softeners and emulsifiers ([0032]), the references does not explicitly disclose from 5% by weight to 60% by weight emulsifying plasticizer wherein the emulsifying plasticizer is acetylated monoglyceride.

Bunczek et al. teach a biodegradable gum base comprising about 5% to about 35 % by weight softener including acetylated monoglyceride (Abstract, C1/L11-13, C2/L60, C9-L62-C10/L1, 51-56). Given Bunczek et al. teach that is was known to use about 5% to about 35% by weight acetylated monoglyceride as a softener in biodegradable gum base compositions, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used about 5% to about 35% by weight acetylated monoglyceride as a softener in the chewing gum base of Gin et al. because doing so would amount to nothing more than the use of a known softener for its intended use in a known environment to accomplish entirely expected results.

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Regarding claim 2, modified Gin et al. disclose all of the claim limitations as set forth above. While Gin et al. disclose a gum base composition comprising about 6.36% to about 6.5% pure poly L-lactic acid polymer, the reference does not disclose wherein the content of the lactic acid polymer is from 10% by weight to less than 50% by weight.

Gin et al. disclose a gum base composition wherein a hydrophilic polymer including pure poly L-lactic acid polymer forms a wet matrix with a flavoring agent resulting in sustained release. Gin et al. disclose that the ratio of hydrophilic polymer to flavor agent is in the range of approximately 1:2 to 1.5:1. Therefore, as flavor intensity is a variable that can be modified, among others, by adjusting the amount of flavoring agent and therefore hydrophilic polymer (i.e. pure poly L-lactic acid polymer), the precise amount of flavoring agent/hydrophilic polymer combination would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of flavoring agent/hydrophilic polymer combination can not be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the thickness amount of flavoring agent and therefore, hydrophilic polymer to obtain the desired flavor intensity in the finished chewing gum product. (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 8, modified Gin et al. disclose all of the claim limitations as set forth above. While modified Gin et al. disclose a gum base composition comprising about 6.36% to about 6.5% pure poly L-lactic acid polymer about 5% to about 35 % by weight softener

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including acetylated monoglyceride (Abstract, C1/L11-13, C2/L60, C9-L62-C10/L1, 51-56), modified Gin et al. does not disclose wherein the ratio by weight of said lactic acid polymer to the acetylated monoglyceride is from 90:10 to 80:20. As elasticity and chewability are variables that can be modified, among others by adjusting the ratio by weight of said lactic acid polymer to the acetylated monoglyceride, the precise ratio would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed ratio by weight of said lactic acid polymer to the acetylated monoglyceride can not be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the ratio by weight of said lactic acid polymer to the acetylated monoglyceride in the chewing gum base composition of modified Gin et al. to obtain the desired chewability or elasticity in the final chewing gum product. (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 9, modified Gin et al. disclose all of the claim limitations as set forth above. While Gin et al. disclose that any conventional gum base can be used ([0032]) the reference does not explicitly disclose a gum base wherein all the ingredients are biologically degradable.

Bunczek et al. teach a gum base composition comprising all biodegradable ingredients (Abstract, C2/L60-61). Therefore, given Gin et al. disclose that any conventional gum base, since Bunczek et al. teach that it was known to make a gum base from all biodegradable

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ingredients, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the biodegradable gum base taught by Bunczek et al. as the gum base in the gum base composition of Gin et al. because doing so would amount to nothing more than the use of a known type of gum base for its intended use in a known environment to accomplish entirely expected results. Further, doing so would produce an environmentally friendly product.

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 1-4, 7-12 and 14-15 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794